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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,686	06/28/2001	Olga Bandman	PC-0044 CIP	7340

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/895,686	BANDMAN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-20 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-6, drawn to polynucletoides, vectors, host cells and recombinant method of producing protein , classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

B. Claims 7-10, in so far as they are drawn to a method for detecting differential expression of nucleic acids in a sample, classified in class 435, subclass 6.

C. Claims 11 and 12, drawn to a method of using cDNA to screen a plurality of molecules or compounds to identify a molecule or compound that specifically binds, classified in class 435, subclass 6, for example.

D. Claims 13 and 14, drawn to polypeptides, classified in class 530, subclass 350, for example.

E. Claims 15 and 16, drawn to a method of using a protein to screen compounds to identify a ligand, classified in class 435, subclass 7.1, for example.

F. Claims 17 and 18, drawn to antibodies and methods of making antibodies and method of purifying antibodies, classified in class 530, subclass 388.22, for example.

G. Claims 19 and 20, drawn to a method for using antibody to detect expression of protein in a sample, classified in class 435, subclass 7.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions A and D are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide is related to the polypeptide by virtue of encoding the same. The polynucleotides have utility for the recombinant production of protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of proteins, such as nucleic acid hybridization assays and gene therapy.

The proteins of invention D are related to the antibodies of invention F by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the protein.

Invention A is related to each of Inventions B, C and E as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cDNAs can be used in a method of detecting the expression

of a nucleic acid molecule in a sample by hybridization, or in a method of screening a plurality of compounds to identify a molecule for compound that specifically binds to the cDNA, or in a method of identifying a compound that binds to a polypeptide (by expressing the nucleic acid in a cell to produce the polypeptide used in the assay), all of which are materially different methods that have different starting compounds, method steps and goals.

Inventions D and invention E are also related as product and process of use. In the instant case, the polypeptides can be used in a method for identifying a compound which binds to a polypeptide, but the polypeptides may also be used in a method of producing antibodies, which is a materially different method.

Inventions F and G are also related as product and process of use. In the instant case, the antibodies can be used in a method of detecting protein in a sample, but the antibodies can also be used in a method of treatment, which is a materially different method.

Inventions A and each of inventions F and G are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cDNAs and antibodies are distinct inventions because they are structurally and functionally distinct chemical compounds, and the cDNAs are not used or defined in the method of detecting protein in a sample.

Invention D is unrelated to each of inventions B, C and G. The polypeptides are not used in the methods of detecting nucleic acids or using nucleic acids to screen for molecules that bind it the nucleic acids or in the method of detecting protein by antibody binding.

Invention F is unrelated to each of inventions B, C and E. The antibodies are not used in the methods of detecting nucleic acids or using nucleic acids to screen for molecules that bind it the nucleic acids or in the method of screening for compounds that may be a ligand for the polypeptide.

Inventions B, C, E and G are also not related to each other. The methods of the different inventions require different starting compounds and have different steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and/or different search and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction Within Groups A-G

4. For the group elected from Groups A-G, further restriction *within* the elected group is required, as follows:

Applicant is advised that claims 1, 8, 9 and 12 are improper Markush claims because the six elements recited therein are proteins and nucleic acids which do not serve common functions which are based upon a common property or special technical feature not found in the prior art. The proteins are patently distinct, having different amino acid sequences, homologies to different proteins, differential tissue expression, and therefore the cDNAs encoding them are also patently distinct.

In order to facilitate the restriction requirement, the six nucleotide/protein/antibody groups are as follows:

I. Polynucleotide having nucleic acid sequences of SEQ ID NO: 7, and polypeptide having the amino acid sequence of SEQ ID NO: 1.

II. Polynucleotide having nucleic acid sequences of SEQ ID NO: 8, and polypeptide having the amino acid sequence of SEQ ID NO: 2.

III. Polynucleotide having nucleic acid sequences of SEQ ID NO: 9, and polypeptide having the amino acid sequence of SEQ ID NO: 3.

IV. Polynucleotide having nucleic acid sequences of SEQ ID NO: 10, and polypeptide having the amino acid sequence of SEQ ID NO: 4.

V. polynucleotides having nucleic acid sequences of SEQ ID NO: 11, and polypeptides having the amino acid sequences of SEQ ID NO: 5.

VI. Polynucleotide having nucleic acid sequences of SEQ ID NO: 12, and polypeptide having the amino acid sequence of SEQ ID NO: 6.

Applicant is advised that this is not a species election.

Although the classifications these various nucleic acid, proteins, antibodies and methods of use are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product, with different sequences and structures and with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because, in the case of the nucleic acid sequences, many are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of the nucleic acid as well as a 'reverse translation' search of the corresponding region of the protein, such that each individual sequence requires two sequence searches which are not required for any of the other sequences. Accordingly, restriction is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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